



## Medical Necessity Criteria for Proton Pump Inhibitors

**Drug Class** - Proton Pump Inhibitors (PPIs). This class includes six products: esomeprazole (Nexium), omeprazole, omeprazole/sodium bicarbonate (Zegerid), lansoprazole (Prevacid), pantoprazole (Protonix), rabeprazole (Aciphex), and dexlansoprazole (Dexilant/Kapidex).

**Background** - After evaluating the relative clinical and cost effectiveness of the PPIs, the DoD P&T Committee recommended that the following medications be designated as non-formulary on the Uniform Formulary. This recommendation has been approved by the Director, TMA.

- Aciphex (rabeprazole)
- Prevacid (lansoprazole)
- Protonix (pantoprazole)
- Zegerid (omeprazole/sodium bicarbonate)
- Dexilant [ *formerly named Kapidex*] (dexlansoprazole)

**Effective Date:** 24 Oct 2007; 28 Sept 2009

Patients currently using a non-formulary agent may wish to consult their doctor to consider a formulary alternative. Both omeprazole and Nexium (esomeprazole) are available at the generic cost share.

### Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. [Mandatory generic policy](#) applies to both formulary and non-formulary medications.
4. Although Nexium (esomeprazole) is a branded product, the DoD P&T Committee recommended that it be made available at a generic cost share based on its similar clinical and cost effectiveness compared to generic omeprazole.
5. Prevacid is available in oral suspension and orally disintegrating tablet formulations and has been approved by the FDA for children as young as 1 year of age. The formulary PPI Nexium is also available as an oral suspension, but is not FDA-approved for pediatric use in children younger than 12 years of age. The only other PPI with a liquid formulation is Zegerid, which has not been studied.
6. [Step therapy / prior authorization \(PA\)](#) requirements apply to all non-formulary drugs in this class, effective 24 Oct 2007. The medical necessity form may NOT be used to meet PA requirements.

### Medical Necessity Criteria for Proton Pump Inhibitors

The non-formulary cost share for Aciphex, Prevacid, Protonix, Zegerid or Dexilant/ Kapidex may be reduced to the formulary cost share IF the patient meets any of the following criteria:

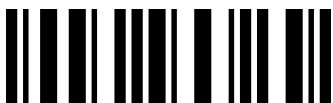
1. Use of ALL of the following formulary alternatives is contraindicated (e.g., due to hypersensitivity): omeprazole (Prilosec, generics) and esomeprazole (Nexium).
2. The patient has experienced significant adverse effects with ALL of the following formulary alternatives: omeprazole (Prilosec, generics) and esomeprazole (Nexium).
3. Use of ALL of the following formulary alternatives has resulted in therapeutic failure: omeprazole (Prilosec, generics) and esomeprazole (Nexium).
4. **Prevacid only** - The patient is younger than 12 years of age.

*Criteria approved through the DoD P&T Committee process May, 2009*

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TRICARE Management Activity,  
a component of the [Military Health System](#)  
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**TRICARE Pharmacy Program Medical Necessity Form for  
Aciphex, Dexilant/Kapindex, Prevacid, Protonix, and Zegerid**



**5551**

This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Proton pump inhibitors (PPIs) on the DoD Uniform Formulary include omeprazole and esomeprazole (Nexium), both of which are available at the formulary cost share. **Aciphex, Dexilant [formerly named Kapindex], Prevacid, Protonix, and Zegerid are non-formulary, but available to many beneficiaries at the non-formulary cost share.** Please note that step therapy/prior authorization requirements (PA) apply to all non-formulary PPIs. PA forms are available on the TRICARE Pharmacy website at [http://pec.ha.osd.mil/forms\\_criteria.php](http://pec.ha.osd.mil/forms_criteria.php). This form may NOT be used to meet step therapy/PA requirements.
- The purpose of this form is to provide information that will be used to determine if the use of a non-formulary PPI instead of either of the formulary PPIs is medically necessary. If a non-formulary PPI is determined to be medically necessary AND the non-Active duty beneficiary has met step therapy/PA requirements, it will be available at the formulary cost share rather than the non-formulary cost share.
- TRICARE will not cover a non-formulary PPI for Active duty service members unless it is determined to be medically necessary instead of a formulary PPI AND the patient has met step therapy/PA requirements, in which case it will be available at no cost share.

<b>MAIL ORDER and RETAIL</b>	<ul style="list-style-type: none"><li>The provider may <b>call: 1-866-684-4488</b> or the completed form may be <b>faxed to: 1-866-684-4477</b></li><li>The patient may attach the completed form to the prescription and <b>mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954</b> or <b>email</b> the form only to: <b>TpharmPA@express-scripts.com</b></li></ul>	<b>MTF</b>	<ul style="list-style-type: none"><li>Non-formulary medications are available at MTFs only if <b>both</b> of the following are met:<ul style="list-style-type: none"><li>The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.</li><li>The non-formulary medication is determined to be medically necessary.</li></ul></li><li>Please contact your local MTF for more information. There are no cost shares at MTFs.</li></ul>

**Step  
1**

**Please complete patient and physician information (please print)**

Patient Name:	_____	Physician Name:	_____
Address:	_____	Address:	_____
Sponsor ID#	_____	Phone #:	_____
Date of Birth:	_____	Secure Fax #:	_____

**Step  
2**

**1. Please indicate which medication is being prescribed:**

- |   |  |
|---|--|
| <input type="checkbox"/> Aciphex (rabeprazole)  | <input type="checkbox"/> Protonix (pantoprazole)                 |
| <input type="checkbox"/> Dexilant [formerly named <b>Kapindex</b> ] (dexlansoprazole) | <input type="checkbox"/> Zegerid (omeprazole/sodium bicarbonate) |
| <input type="checkbox"/> Prevacid (lansoprazole)                                      |  |

**2. Please explain why the patient cannot be treated with a formulary alternative: omeprazole, esomeprazole (Nexium).**

Please indicate which of the reasons below (1-4) applies to each of the formulary PPIs listed in the table. You **MUST** circle a reason AND supply a specific written clinical explanation for EACH formulary alternative.

Formulary Alternative	Reason	Clinical Explanation
Omeprazole	1 2 3 4	
Esomeprazole (Nexium)	1 2 3 4	

- Use of the formulary alternative is contraindicated (e.g., due to hypersensitivity).
- The patient has experienced significant adverse effects from the formulary alternative.
- Use of the formulary alternative has resulted in therapeutic failure.
- Prevacid only** – The patient is younger than 12 years of age.

**Step  
3**

**I certify that the above is correct to the best of my knowledge (Please sign and date):**

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date